



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO. 028685-0104

Applicant: Carl J. PEPINE et al.
Title: COMBINATION DRUG THERAPY FOR TREATING
HYPERTENSION
Appl. No.: 10/816,461
Filing Date: 04/01/2004
Examiner: Unassigned
Art Unit: 1614

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to OG Notice dated August 5, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-1741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-1741.

Respectfully submitted,

October 18, 2004

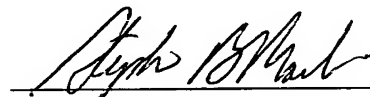
Date

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone: (202) 672-5569

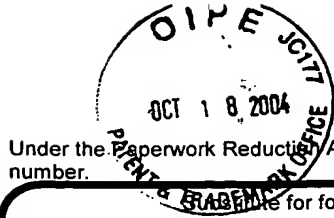
Facsimile: (202) 672-5399



Stephen B. Maebius

Attorney for Applicant

Registration No. 35,264



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: October 18, 2004 (use as many sheets as necessary)		Complete if Known	
		Application Number	10/816,461
		Filing Date	TBD
		First Named Inventor	Carl J. PEPINE et al.
		Group Art Unit	1614
		Examiner Name	Unassigned
		Attorney Docket Number	028685-0104

Sheet	1	of	5
-------	---	----	---

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		U.S. 4,933,361		Urbach et al.	Jun-12-1990	
		U.S. 5,098,910		Becker et al.	Mar-24-1992	
		U.S. 5,236,933		Becker et al.	Apr-17-1993	
		U.S. 5,366,994		Becker et al.	Nov-22-1994	
		U.S. 5,403,856		Henning et al.	Apr-04-1995	
		U.S. 5,500,434		Becker et al.	Mar-19-1996	
		U.S. 5,684,016		Henning et al.	Nov-04-1997	
		U.S. 5,721,244		Becker et al.	Feb-24-1998	
		U.S. 5,744,496		Henning et al.	Apr-28-1998	
		U.S. 5,747,504		Henning et al.	May-05-1998	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		H.A. PUNZI ET AL., The Treatment of Severe Hypertension with Trandolapril, Verapamil, and Hydrochlorothiazide, <i>Journal of Human Hypertension</i> (1997) 11, 477-481.	
		J. SKOULARIGIS ET AL., Once-Daily Fixed Dose Combinations of Verapamil and Trandolapril in Black Patients with Mild to Moderate Hypertension: a New Choice for First Line Treatment, <i>International Journal of Clinical Pharmacology and Therapeutics</i> , Vol. 35, No. 2 (1997), 51-55.	
		C.J. MURRAY ET AL., Global Mortality, Disability, and the Contribution of Risk Factors: Global Burden of Disease Study, <i>Lancet</i> 1997; 349: 1436-42.	
		EUROASPIRE II Study Group. Lifestyle and Risk Factor Management and Use of Drug Therapies in Coronary Patients From 15 Countries; Principal Results From EUROASPIRE II Euro Heart Survey Programme. <i>Eur Heart J</i> 2001; 22: 554-72.	
		C.J.L. MURRAY ET AL., Effectiveness and Costs of Interventions to Lower Systolic Blood Pressure and Cholesterol: a Global and Regional Analysis on Reduction of Cardiovascular-Disease Risk, <i>Lancet</i> 2003; 361: 717-25.	
		SHEP Cooperative Research Group. Prevention of Stroke by Antihypertensive Drug Treatment in Older Persons with Isolated Systolic Hypertension: Final Results of the Systolic Hypertension in the Elderly Program (SHEP), <i>JAMA</i> 1991; 265: 3255-64.	
		B. DAHLOF ET AL., Morbidity and Mortality in the Swedish Trial in Old Patients with Hypertension (STOP-Hypertension), <i>Lancet</i> 1991; 338: 1281-5.	
		MRC Working Party. Medical Research Council Trial of Treatment of Hypertension in Older Adults: Principal Results, <i>Br Med J</i> 1992; 304: 405-12.	
		R. COLLINS ET AL., Blood Pressure, Antihypertensive Drug Treatment and the Risks of Stroke and of Coronary Heart Disease, <i>Br Med Bull</i> 1994; 50: 272-98.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: October 18, 2004 (use as many sheets as necessary)				Application Number	10/816,461
				Filing Date	TBD
				First Named Inventor	Carl J. PEPINE et al.
				Group Art Unit	1614
				Examiner Name	Unassigned
Sheet	2	of	5	Attorney Docket Number	028685-0104

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		B.M. PSATY, ET AL., Health Outcomes Associated with Antihypertensive Therapies Used as First-Line Agents, <i>JAMA</i> 1997; 277:739-45.	
		J.A. STAESSEN, ET AL., for the Systolic Hypertension in Europe (Syst-Eur) Trial Investigators. Randomised Double-Blind Comparison of Placebo and Active Treatment for Older Patients with Isolated Systolic Hypertension, <i>Lancet</i> 1997; 350: 757-64.	
		K.K. TEO, ET AL., Long-Term Effects of Cholesterol Lowering and Angiotensin-Converting Enzyme Inhibition on Coronary Atherosclerosis: the Simvastatin/Enalapril Coronary Atherosclerosis Trial (SCAT), <i>Circulation</i> 2000; 102: 1748-54.	
		B. PITT, ET AL., Effect of Amlodipine on the Progression of Atherosclerosis and the Occurrence of Clinical Events, <i>Circulation</i> 2000; 102: 1503-10.	
		L. HANSSON, ET AL., Effect of Angiotensin-Converting-Enzyme Inhibition Compared with Conventional Therapy on Cardiovascular Morbidity and Mortality in Hypertension: the Captopril Prevention Project (CAPPP) Randomised Trial, <i>Lancet</i> 1999; 353: 611-6.	
		M.J. BROWN, ET AL., Morbidity and Mortality in Patients Randomised to Double-Blind Treatment with a Long-Acting Calcium-Channel Blocker or Diuretic in the International Nifedipine GITS study: Intervention as a Goal in Hypertension Treatment (INSIGHT), <i>Lancet</i> 2000; 356: 366-72.	
		L. HANSSON, ET AL., Randomised Trial of Effects of Calcium Antagonists Compared with Diuretics and Beta-Blockers on Cardiovascular Morbidity and Mortality in Hypertension: the Nordic Diltiazem (NORDIL) Study, <i>Lancet</i> 2000; 356: 359-65.	
		L. HANSSON, ET AL, for the STOP-Hypertension-2 Study Group. Randomised Trial of Old and New Antihypertensive Drugs in Elderly Patients: Cardiovascular Mortality and Morbidity the Swedish Trial in Old Patients with Hypertension-2 study, <i>Lancet</i> 1999; 354:1751-6.	
		L. HANSSON, ET AL., Effects of Intensive Blood-Pressure Lowering and Low-Dose Aspirin in Patients with Hypertension: Principal Results of the Hypertension Optimal Treatment (HOT) Randomised Trial, <i>Lancet</i> 1998; 351: 1755-62.	
		UK Prospective Diabetes Study Group, Tight Blood Pressure Control and Risk of Macrovascular and Microvascular Complications in Type 2 Diabetes: UKPDS 38, <i>BMJ</i> 1998; 317: 703-20.	
		UK Prospective Diabetes Study Group, Efficacy of Atenolol and Captopril in Reducing Risk of Macrovascular and Microvascular Complications in Type 2 Diabetes: UKPDS 39, <i>BMJ</i> 1998; 317: 713-20.	
		A. ZANCHETTI, ET AL., The Verapamil in Hypertension and Atherosclerosis Study (VHAS): Results of Long-Term Randomised Treatment with Either Verapamil or Chlorthalidone on Intima-Media Thickness, <i>J Hyperten</i> 1998; 16: 1667-76.	
		R.O. ESTACIO, ET AL., The Effect of Nisoldipine as Compared with Enalapril on Cardiovascular Outcomes in Patients with Non-Insulin-Dependent Diabetes and Hypertension, <i>N Engl J Med</i> 1998; 338: 645-52.	
		The ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group, Major Outcomes in High-Risk Hypertensive Patients Randomized to Angiotensin-Converting Enzyme Inhibitor or Calcium Channel Blocker vs Diuretic: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), <i>JAMA</i> 2002; 288: 2981-97.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: October 18, 2004 (use as many sheets as necessary)		Application Number	10/816,461
		Filing Date	TBD
		First Named Inventor	Carl J. PEPINE et al.
		Group Art Unit	1614
		Examiner Name	Unassigned
Sheet 3 of 5	Attorney Docket Number	028685-0104	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		B. NEAL, ET AL., Effects of ACE Inhibitors, Calcium Antagonists, and Other Blood-Pressure-Lowering Drugs: Results of Prospectively Designed Overviews of Randomised Trials, Blood Pressure Lowering Treatment Trialists' Collaboration, <i>Lancet</i> 2000; 356: 1955-64.	
		H.R. BLACK, ET AL., Baseline Characteristics and Early Blood Pressure Control in the CONVINC Trial, <i>Hypertension</i> 2001; 37: 12-8.	
		B. DAHLÖF, ET AL., for the LIFE study group, Cardiovascular Morbidity and Mortality in the Losartan Intervention For Endpoint Reduction in Hypertension Study (LIFE): a Randomized Trial Against Atenolol, <i>Lancet</i> 2002; 359: 995-1003.	
		The Fifth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, <i>Arch Intern Med</i> 1993; 153: 154-183.	
		Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, The Sixth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI), <i>Arch Intern Med</i> 1997; 157: 2413-46.	
		The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, <i>Arch Intern Med</i> 1997; 157: 2413-46 [Erratum, <i>Arch Intern Med</i> 1998; 158: 573].	
		C. ARAUZ-PACHECO, ET AL., The Treatment of Hypertension in Adult Patients with Diabetes, <i>Diabetes Care</i> 2002; 25: 134-47.	
		S.C. SMITH JR, ET AL., AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 update, <i>Circulation</i> 2001; 104: 1577-79.	
		C.J. PEPINE, ET AL., for the INVEST Investigators, Rationale and Design of the International Verapamil SR/Trandolapril Study (INVEST): an Internet-based Randomized Trial in Coronary Artery Disease Patients with Hypertension, <i>J Am Coll Cardiol</i> 1998; 32: 1228-37.	
		L. HANSSON, ET AL., Prospective Randomized Open Blinded End-Point (PROBE) Study, A Novel Design for Intervention Trials, <i>Blood Press</i> 1992; 1: 113-9.	
		R. MARKS, ET AL., Enhancing Clinical Trials on the Internet: Lessons from INVEST, <i>Clin Cardiol</i> 2001; 24 (11 suppl): V17-23.	
		R. COOPER-DEHOFF, ET AL., Electronic Prescribing via the Internet for a Coronary Artery Disease and Hypertension Megatrial, <i>Clin Cardiol</i> 2001; 24 (11 suppl): V14-V6.	
		V.L. BURT, ET AL., Prevalence of Hypertension in the US Adult Population: Results From the Third National Health and Nutrition Examination Survey, 1988-1991. <i>Hypertension</i> 1995; 25: 305-13.	
		P.S. SEVER, ET AL., for the ASCOT Investigators, Rationale, Design, Methods and Baseline Demography of Participants of the Anglo-Scandinavian Cardiac Outcomes Trial, <i>J Hypertens</i> 2001; 19: 1139-47.	
		M. EPSTEIN, The Calcium Antagonist Controversy: the Emerging Importance of Drug Formulation as a Determinant of Risk, <i>Am J Cardiol</i> 1997; 79 (suppl 10A): 9-19.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: October 18, 2004 (use as many sheets as necessary)				Application Number	10/816,461
				Filing Date	TBD
				First Named Inventor	Carl J. PEPINE et al.
				Group Art Unit	1614
				Examiner Name	Unassigned
Sheet	4	of	5	Attorney Docket Number	028685-0104

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		C.J. PEPINE, The Role of Calcium Antagonists in Ischaemic Heart Disease, <i>Eur Heart J</i> 1995; 16 (suppl H): 19-24.	
		S. YUSUF, ET AL., for the Heart Outcomes Prevention Evaluation (HOPE) Study Investigators. Effects of an Angiotensin-Converting-Enzyme Inhibitor, Ramipril, on Cardiovascular Events in High-Risk Patients, <i>N Engl J Med</i> 2000; 342: 145-53.	
		G.L. BAKRIS, ET AL., Effects of an ACE Inhibitor/Calcium Antagonist Combination on Proteinuria in Diabetic Nephropathy, <i>Kidney Int</i> 1998; 54: 1283-9.	
		AD Hoc Subcommittee of the Liaison Committee of the World Health Organisation and the International Society of Hypertension (Alderman M, Arakawa K, Beilin L, et al.), Effects of Calcium Antagonists on the Risks of Coronary Heart Disease, Cancer and Bleeding, <i>J Hypertens</i> 1997; 15: 105-15.	
		L.M. WING, ET AL., A Comparison of Outcomes with Angiotensin-Converting-Enzyme Inhibitors and Diuretics for Hypertension in the Elderly, <i>N Engl J Med</i> 2003; 348: 583-92.	
		G.L. BAKRIS, ET AL., Preserving Renal Function in Adults with Hypertension and Diabetes: a Consensus Approach, National Kidney Foundation Hypertension and Diabetes Executive Committees Working Group, <i>Am J Kidney Dis</i> 2000 36: 646-61.	
		C.D. FURBERG, ET AL., Nifedipine: Dose-Related Increase in Mortality in Patients with Coronary Heart Disease, <i>Circulation</i> 1995; 92: 1326-31.	
		B.M. PSATY, ET AL., The Risk of Myocardial Infarction Associated with Antihypertensive Drug Therapies, <i>JAMA</i> 1995; 274: 620-5.	
		M. PAHOR, ET AL., Health Outcomes Associated with Calcium Antagonists Compared with Other First-Line Antihypertensive Therapies: a Meta-Analysis of Randomised Controlled Trials, <i>Lancet</i> 2000; 356: 1949-54.	
		Chalmers J, MacMahon S, Mancina G, et al. Guidelines for the management of hypertension. <i>Clin Exp Hypertens</i> . 1999; 21:1009-1060.	
		Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. <i>JAMA</i> . 2003; 289:2560-2572.	
		Hennekens CH, Albert CM, Godfried SL, Gaziano JM, Buring JE. Adjunctive drug therapy for acute myocardial infarction-evidence from clinical trials. <i>N Engl J Med</i> . 1996; 335:1660-1667.	
		Messerli FH, Grossman E, Goldbourt U. Are β -blockers efficacious as first-line therapy for hypertension in the elderly? <i>JAMA</i> . 1998; 279:1903-1907.	
		Pepine CJ, Faich G, Makuch R. Verapamil use in patients with cardiovascular disease: an overview of randomized trials. <i>Clin Cardiol</i> . 1998; 21:633-641.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: October 18, 2004 (use as many sheets as necessary)				Complete if Known	
				Application Number	10/816,461
				Filing Date	TBD
				First Named Inventor	Carl J. PEPINE et al.
				Group Art Unit	1614
				Examiner Name	Unassigned
				Attorney Docket Number	028685-0104
Sheet	5	of	5		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		Ruilope LM, de la Sierra A, Moreno E, et al. Prospective comparison of therapeutical attitudes in hypertensive type 2 diabetic patients uncontrolled on monotherapy. a randomized trial: the EDICTA study. <i>J Hypertens.</i> 1999; 17:1917-1923.	
		Karlberg BE, Andrup M, Oden A, for the Swedish TARKA trialists. Efficacy and safety of a new long-acting drug combination, trandolapril/verapamil as compared to monotherapy in primary hypertension. <i>Blood Press.</i> 2000; 9:140-145.	
		PROCOPA Study Group. Dissociation between blood pressure reduction and fall in proteinuria in primary renal disease. <i>J Hypertens.</i> 2002; 20:729-737.	
		Holzgrevé H, Nakov R, Beck K, Janka HU. Anti-hypertensive therapy with verapamil SR plus trandolapril versus atenolol plus chlorthalidone on glycemic control. <i>Am J Hypertens.</i> 2003; 16:381-386.	
		Brenner BM, Cooper ME, De Zeeuw D, et al. Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. <i>N Engl J Med.</i> 2001; 345:861-869.	
		Parving HH, Lehnert H, Bröchner-Mortensen J, et al. The effect of irbesartan on the development of diabetic nephropathy in patients with type 2 diabetes. <i>N Engl Med.</i> 2001; 345:870-878.	
		Wright JT Jr, Bakris G, Greene T, et al. Effect of blood pressure lowering and antihypertensive drug class on progression of hypertensive kidney disease: results from the AASK trial. <i>JAMA.</i> 2002; 19:2421-2431.	
		INVEST information pack. Available at: http://www.medicine.ufl.edu/cardio/research/invest_info/invest_definitions.shtml . Accessed October 4, 2003.	
		MERIT-HF Study Group. Effect of metoprolol CR/XL in chronic heart failure. <i>Lancet.</i> 1999; 353:2001-2007.	
		Dargie HJ, Lechat P. The Cardiac Insufficiency Bisoprolol Study II (CIBIS-II): a randomised trial. <i>Lancet.</i> 1999; 353:9-13.	
		Packer M, Coats AJS, Fowler MB, et al. Effect of carvedilol on survival in severe chronic heart failure. <i>N Engl J Med.</i> 2001; 344:1651-1658.	
		Lewington S, Clarke R, Qizilbash N, Peto R, Collins R. Age-specific relevance of usual blood pressure to vascular mortality. <i>Lancet.</i> 2002; 360:1903-1913.	
		Cooper-DeHoff R, Bakris G, Cohen J, et al. Reduced risk of new onset diabetes in hypertensive coronary artery disease patients treated with a calcium antagonist vs a beta blocker regimen: the International Verapamil/Trandolapril Study. <i>Circulation.</i> 2003; 108:IV-750.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.